

REMARKS

Claims 27-43 are currently pending in the application. By this amendment, claims 27, 31, 33-35, 43 and 57 will have been amended for the Examiner's consideration and claims 28-30 and 36-42 will have been canceled. Claims 1-26, 44-55 and 56, directed to a non-elected invention, have been withdrawn by the Examiner. Moreover, Applicant notes that while the scope of claim 27 has been changed by the amendment, the claim is still within the group of invention previously elected. Applicant further notes the present amendments to independent claim 27 and to the dependent claims 31, 33-35, 43 and 57 are believed to overcome all the Examiner's 35 U.S.C. §112, First Paragraph and Second Paragraph rejections. Applicant submits no new matter will have been introduced.

Accordingly, by the present amendments and remarks, Applicant submits that the rejections have been overcome, and respectfully request reconsideration of the outstanding Office Action and allowance of the instant application.

Amendment Fully Supported by the Original Disclosure

The above amendments do not add new matter to the application and are fully supported by the specification. For example, support for amending independent claim 27 is provided at paragraphs [0030] to [0049] of the specification. Applicant notes that the subject matter of canceled claims 28-30 will have been inserted into the independent claim 27. Further, Applicant notes the amendments to independent claim 27 will have been made to address the Examiner's 35 USC § 112, First Paragraph and Second Paragraph rejections presented in the present Office Action (see pages 3-5).

Further, claims 31, 33-35, 43 and 57 will have been amended to address dependency issues, grammatical errors and antecedent issues.

Applicant submits claim 35 will have been amended to address the Examiner's rejections present in the present Office Action (see pages 4-5).

Applicant also submits, support for new claims 58 and 59 are provided at paragraphs [0030] to [0049] of the specification.

Applicant respectfully requests reconsideration and timely withdrawal of the pending rejections for the reasons discussed below.

Acknowledgement of Cited Items

Applicant notes with appreciation the Examiner's consideration of the documents cited in the Information Disclosure Statement filed on February 19, 2004 and the Supplemental Information Disclosure Statement filed on October 24, 2005, by the return of the initialed and signed copies of the PTO-1449 Forms.

Preliminary Matter concerning NEW claims 56 and 57

Applicant notes that new claims 56 and 57 were not addressed by the Examiner in the present Office Action dated December 13, 2007.

Independent claim 1 will have been withdrawn by the Examiner for being directed to an non-elected invention, and because claim 56 depends from independent claim 1, Applicant will have withdrawn claim 56 for being directed to an non-elected invention.

However, independent claim 27 was not withdrawn by the Examiner and because claim 57 depends from independent claim 27, Applicant respectfully requests

the Examiner to examine the subject matter of dependent claim 57 in the next official communication.

35 USC § 112, First Paragraph rejections are Believed Moot

Claims 27-43 were rejected under 35 U.S.C. §112, First Paragraph, Enablement, Applicant respectfully transverses this rejection.

Applicant respectfully submits, that the Examiner's rejection of claims 27-43 under 35 U.S.C. §112, First Paragraph, Enablement, is moot in view of Applicant's amendment of claims 27, 31, 33-35, 43. Applicant further notes rejected claims 28-30 and 36-42 have been canceled.

As a preliminary matter, the entire disclosure, including the drawings, provide sufficient disclosure of what is claimed, as currently amended. The terms relating to the method that "create a reagent mixture comprising known reagent in known quantities, with each reagent having a known thermodynamic acid dissociation constant, and then to optimize this reagent mixture by changing all parameters of the mixture, including the reagents (with their respective acid dissociation constants) and their quantities, in order to get the desired pH range" are presented in the specification, and the specification provides a complete understanding for one ordinary skilled in the art to make and or use the invention. Specifically, the specification clearly describes Applicant's above-noted method, as disclosed in paragraphs [0030] to [0049] of the Specification.

Applicant respectfully notes that such language contains a full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

As is indicated in MPEP 2164.01:

"[t]he test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosure coupled with information known in the art without undue experimentation. United States v. Teletronics, Inc., 857 F.2d 778, 8 USPQ2d 1217 (Fed. Cir. 1988); In re Stephens, 188 USPQ 659 (CCPA 1976). The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. In re Angstadt, 190 USPQ 214 (CCPA 1976). An extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance. In re Colianni, 195 USPQ 150 (CCPA 1977) (Miller, J., concurring). The experimentation required, in addition to not being undue, must not require ingenuity beyond that expected of one of ordinary skill in the art. In re Angstadt, supra. For example, in one instance a "few hours" of experimentation to determine process parameters was not considered to be undue in view of the nature of the invention (preparation of oxygenated hydrocarbons). In re Borkowski, 164 USPQ 642 (CCPA 1970). In Tabuchi v. Nubel, 194 USPQ 521 (CCPA 1977) a screening procedure which took 15 calendar days was not considered undue experimentation because the test was both simple and straightforward and because of its demonstrated success in producing the desired result.

Applicant has disclosed the method as discussed-above, so as to provide one skilled in the art to make and or use the claimed invention without undue experimentation. Such information coupled with the skill and knowledge that one of ordinary skill in the art would have regarding the method as discussed-above is more than sufficient to enable the claimed invention and certainly would not require undue experimentation.

Applicant reminds the Examiner of the guidance provided in MPEP 2164.04, which states that:

“...a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of 35 USC112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.”

Furthermore, as noted-above, Applicant submits, that the Examiner's rejection of claims 27-43 under 35 U.S.C. §112, First Paragraph, Enablement, is moot in view of Applicant's amendment of claims 27, 31, 33-35, 43.

Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of the above-noted claims under 35 U.S.C. § 112, first paragraph.

35 U.S.C. §112, Second Paragraph Rejections are Believed Moot

The Examiner has rejected claims 27-43 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to distinctly claim the subject matter which Applicant regards as the invention.

While Applicant disagrees with each of the Examiner's assertions, by the present amendment, Applicant has amended claims 27, 31, 33-35, 43 to even more clearly recite the features of the invention and in order to render moot the Examiner's rejection under 35 U.S.C. 112, second paragraph. Applicant further notes that rejected claims 28-30 and 36-42 have been canceled.

Accordingly, Applicant respectfully requests reconsideration and timely withdrawal of the instant rejection under 35 U.S.C. 112, second paragraph for claims 27, 31, 33-35, 43, as currently amended.

35 U.S.C. § 102 / 103 Rejection

Claims 27-43 were rejected under 35 U.S.C. § 102(b) as being anticipated by King *et al.* (Appl. Spectr., 1990, IDS) (hereafter "KING"), Lin *et al.* (Anal. Chim. Acta, 2000, IDS) (hereafter "LIN") and claims 27 and 30 were rejected as being anticipated by Baldini *et al.* (Sensors and Actuators B, 1995) (hereafter "BALDINI") or alternatively claim 43 was rejected under 35 U.S.C. § 103(a) as obvious over KING. The Examiner asserts that while KING does not show all the claimed features of the instant invention including the optimizing an absolute concentration of the reagent mixture in error analysis, optimizing the concentration of the reagent is conventional procedure in analytical spectroscopy (the Examiner provides no reference substantiating such assertion, see page 8 of the instant Office Action). Applicant respectfully traverses the Examiner's assertions, in view of the current amendment.

Applicant's independent claim 1, as currently amended, recites *inter alia*,

- d. identifying the spectroscopic noise of a spectral analyzer to be used for the pH measurement;
- e. mixing known relative concentrations of two or more reagents of the plurality of reagents to create the one or more sets of reagents, wherein the one or more sets of reagents is capable of measuring one of the pH at a higher accuracy than each reagent individually for a given pH range or measuring pH over a broader range than the individual reagent for the same accuracy;
- f. optimizing the one or more sets of reagents with an optimization algorithm to satisfy pH accuracy constraint over the targeted pH measurement

- range of the sample and determine one of optimum values for relative concentrations or spectral channels;
- g. repeating steps (e) thru (f) if unable to satisfy target pH measurement range and pH accuracy constraint for the one or more sets of reagents; and
- h. characterizing the one or more optimized reagent set.

Applicant submits that neither KING nor LIN nor BALDINI, or their combination discloses or suggests at least these features.

KING use experimental measurements to determine Gaussian components of the individual acid and base forms of the dye spectra and use these components to calculate the spectra and forward model dye responses in various pH media. As an example, in the KING method they forward model the response of a two-dye mixture as a 3D plot of Absorbance, pH and wavelength. Then, KING probes the sensitivity of the optical density ratio to pH to pick out optimum wavelengths. However, contrary to the Examiner's assertions, in the KING method there is no automated optimization algorithm used and it requires generating mixed indicator spectra for various concentration combinations to get the optimum values. Moreover, the role of spectral noise, which we show to be important, has not been considered in the dye formulation process of KING. In particular, Applicant's claimed method uses an algorithm that automatically optimizes for indicator concentrations and pKa (could also do wavelength if needed) such that the sensitivity over any desired pH range is maximized. The algorithm typically takes a second or less to converge.

Applicant submits this document fails to teach or suggest steps (d) thru (g), as noted-above, which is recited in independent claim 27, as currently amended.

Because the applied reference of KING fails to disclose or suggest at least the above-noted features of the instant invention, Applicant submits that the applied art fails to show each and every recited feature of the present invention, as currently amended, such that this document cannot provide an adequate evidentiary basis to support a rejection of anticipation under 35 U.S.C. §102(b) or obviousness under 35 U.S.C. § 103(a).

Furthermore, LIN does not cure the deficiencies of KING and merely discloses using linearity of absorbance at one chosen wavelength vs. pH as the criteria for optimization. However, contrary to the Examiner's assertions, in the LIN method this linear fit is then the approximate model used subsequently to predict pH from absorbance measurements in unknown pH samples. Moreover, Applicant notes that the standard deviation as defined by LIN refers to the deviation of the true spectral response from a linear model and is a systematic error arising out of model approximation. It is a single number calculated for the entire pH interval and so does not indicate the precision at each pH point. Random errors from experimental data will further increase this standard deviation as disclosed by LIN. This is in direct contrast to Applicant's claim invention which discloses the concept of standard deviation that arises from noise in spectral data and allows giving a precision to be expected for each pH point. LIN, however, fails to teach or suggest the subject matter noted above as deficient in KING.

Applicant submits this document fails to teach or suggest steps (d) thru (g), as noted-above, which is recited in independent claim 27, as currently amended.

Because the applied reference of LIN fails to disclose or suggest at least the above-noted features of the instant invention, Applicant submits that the applied art fails to show each and every recited feature of the present invention, as currently amended, such that this document cannot provide an adequate evidentiary basis to support a rejection of anticipation under 35 U.S.C. §102(b) or obviousness under 35 U.S.C. § 103(a).

Moreover, BALDINI does not cure the deficiencies of either LIN or KING, and discloses a method for the development of an optical-fiber sensor for monitoring pH in the foregut in the extended range 1.0 to 8.0. However, contrary to the Examiner's assertions, in the BALDINI method nothing teaches or suggests the subject matter noted-above as deficient in LIN and KING.

Applicant further submits this document fails to teach or suggest steps (d) thru (g), as noted-above, which is recited in independent claim 27, as currently amended.

Because the applied reference of LIN fails to disclose or suggest at least the above-noted features of the instant invention, Applicant submits that the applied art fails to show each and every recited feature of the present invention, as currently amended, such that this document cannot provide an adequate evidentiary basis to support a rejection of anticipation under 35 U.S.C. §102(b) or obviousness under 35 U.S.C. § 103(a).

Accordingly, Applicant requests that the Examiner reconsider and withdraw the instant rejection.

Further, Applicant submits that claims 31, 33-35, 43 are allowable at least for the reason that these claims depend from allowable base claim and because these claims recite additional features that further define the present invention.

Accordingly, Applicant requests that the Examiner reconsider and withdraw the rejection of claims 27, 31, 33-35, 43 indicate that these claims are allowable.

New Claims are Believed Allowable

Applicant's newly submitted claims 58 and 59 are allowable over the art of record at least for the reasons set forth above. In particular, new dependent claim 58, recites, in part:

"wherein the reagents show similar direction of spectral shift with changes in pH."
and, new dependent claim 59, recites, in part:

"identifying the spectroscopic noise includes one of signal to noise ratio of spectral signal or standard deviation and the optical density."

Applicant submits that neither KING nor LIN nor BALDINI, or their combination or any art document of record teaches or suggests the combination of features recited in a independent claim 27, as currently amended. Claims 58 and 59 are also allowable over KING, LIN or BALDINI at least because of their dependency from allowable base independent claim 27, and because these claims further define the invention over the art of record. Therefore, Applicant requests an indication of allowance in the next Official Action.

CONCLUSION

In view of the foregoing, it is submitted that none of the references of record, either taken alone or in any proper combination thereof, anticipate or render obvious the Applicant's invention, as recited in each of claims 27, 31, 33-35, 43. The applied references of record have been discussed and distinguished, while significant claimed features of the present invention have been pointed out.

Further, any amendments to the claims which have been made in this response and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

Accordingly, reconsideration of the outstanding Office Action and allowance of the present application and all the claims therein are respectfully requested and now believed to be appropriate.

Should the Examiner have any questions or comments, he is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,
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